A SYSTEM AND METHOD FOR IMMOBILIZING ADJACENT SPINOUS PROCESSES

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PRIORITY CLAIM

[0001] This application claims priority to the following U.S. Provisional Patent Application:

[0002] U.S. Provisional Patent Application No. 60/446,868, entitled "A System and Method for Immobilizing Adjacent Spinous Processes," Attorney Docket No. KLYC-01086US0, filed February 12, 2003.

CROSS-REFERENCED CASES

[0003] The following U.S. Patent Applications are cross-referenced and incorporated herein by reference:

[0004] U.S. Patent Application No. 09/829,321, entitled "SPINE FIXATION DEVICE AND METHOD" by David Yun, filed April 9, 2001 (Attorney Docket No. KLYC-01049US0);

[0005] U.S. Provisional Patent Application No. 60/421,921, entitled "INTERSPINOUS PROCESS APPARATUS AND METHOD WITH A SELECTABLY EXPANDABLE SPACER" by James F. Zucherman, Ken Y. Hsu, and Charles J. Winslow, filed October 29, 2002 (Attorney Docket No. KLYC-01056US0);

[0006] U.S. Patent Application No. 09/579,039, entitled SUPPLEMENTAL SPINE FIXATION DEVICE AND METHOD by James F. Zucherman, Ken Y. Hsu, Charles J. Winslow and Henry A. Klyce, filed May 26, 2000 (Attorney Docket No. KLYC-01033US0);

[0007] U.S. Patent Application No. 09/842,819, entitled SUPPLEMENTAL SPINE FIXATION DEVICE AND METHOD by James F. Zucherman, Ken Y. Hsu, Charles J. Winslow and Henry A. Klyce, filed April 26, 2001 (Attorney Docket No. KLYC-01033US4);

[0008] U.S. Patent Application No. 09/982,418, entitled SUPPLEMENTAL SPINE FIXATION DEVICE AND METHOD by James F. Zucherman, Ken Y. Hsu, Charles J. Winslow, Steve Mitchell, Scott Yerby and Henry A. Klyce, filed October 18, 2001 (Attorney Docket No. KLYC-01033US5);

[0009] U.S. Provisional Patent Application No. 60/306,262, entitled SUPPLEMENTAL SPINE FIXATION DEVICE AND METHOD by James F. Zucherman, Ken Y. Hsu, Charles J. Winslow, Steve Mitchell, Scott Yerby and Henry A. Klyce, filed July 18, 2001 (Attorney Docket No. KLYC-01033US3);

[0010] U.S. Provisional Patent Application No. 60/421,915, entitled INTERSPINOUS PROCESS IMPLANT WITH RADIOLUCENT SPACER AND LEAD-IN TISSUE EXPANDER by James F. Zucherman, Ken Y. Hsu, Charles J. Winslow, John Flynn and Steve Mitchell, filed October 29, 2002 (Attorney Docket No. KLYC-01077US0); and

[0011] U.S. Patent Application No. 10/230,505, entitled DEFLECTABLE SPACER FOR USE AS AN INTERSPINOUS PROCESS IMPLANT AND METHOD by James F. Zucherman, Ken Y. Hsu, Charles J. Winslow and John Flynn, filed August 29, 2002 (Attorney Docket No. KLYC-01056USB).

Technical Field

[0012] The present invention relates to methods and systems for immobilizing adjacent spinous processes which, by way of example only, supplement a primary spine fusion device, such as an interbody fusion device.

Background

[0013] A common procedure for handling pain associated with degenerative spinal disk disease uses devices for fusing together two or more adjacent vertebral bodies. The procedure is known by a number of terms, one of which is interbody fusion. Interbody fusion can be accomplished through the use of a number of methods and devices known in the art. These methods and devices include screw arrangements, solid bone implant methodologies, and fusion devices which include a cage or other mechanism packed with bone and/or bone growth inducing substances. One or more of the above are implanted between adjacent vertebral bodies in order to fuse the vertebral bodies together, thereby alleviating associated pain.

[0014] It can be advantageous to associate with such primary fusion devices and methods, supplemental devices which assist in the fusion process. These supplemental devices assist during the several month period when bone from the adjacent vertebral bodies is growing together through the primary fusion device in order to fuse the adjacent vertebral bodies. During this period it is advantageous to have the vertebral bodies held immobile with respect to each other so that sufficient bone growth can be established.

[0015] Such supplemental devices can include hook and rod arrangements, screw arrangements, and a number of other devices which include straps, wires, and bands, all of which are used to immobilize one portion of the spine relative to another. All of these devices generally require extensive surgical procedures in addition to the extensive procedure surrounding the primary fusion implant.

[0016] It is advantageous for a device and procedure for supplemental spine fixation to be as simple and easy to perform as possible, and optimally such a device and procedure leaves bone, ligament, and other tissue which comprise and surround the spine intact.

Brief Description of the Drawings

[0017] Further details of embodiments of the present invention are explained with the help of the attached drawings in which:

[0018] **FIG. 1** is a side view of a system in accordance with one embodiment of the present invention positioned about adjacent spinous processes;

[0019] **FIG. 2A** is a top view of the system shown in **FIG. 1**;

[0020] **FIG. 2B** is a close-up view of two grips positioned on opposite sides of a spinous process as shown in **FIG. 2A**;

[0021] **FIG. 3** is a side view of an alternative embodiment of the invention with an expanding spacer;

[0022] **FIG. 4A** is a side view of an alternative embodiment of the invention with a slot for positioning a pin having lobed cut-outs;

[0023] **FIG. 4B** is a side view of an alternative embodiment of the invention with a slot for positioning a pin having a knurled periphery; and

[0024] **FIG. 5** is a representation of a method for immobilizing adjacent spinous processes in accordance with one embodiment of the present invention.

<u>Detailed Description</u>

[0025] **FIGs. 1-2B** illustrate a system for immobilizing adjacent spinous processes in accordance with one embodiment of the present invention. The system **100** comprises a scaffold formed by two plates **104a,b** adjustably connected by pins **110** inserted through slots **106** in each plate. Each plate **104a,b** is positioned generally along a plane parallel to a plane formed by the major axis of the spinous processes, with a first plate **104a** positioned on one side of protruding adjacent spinous processes, and a second plate **104b** positioned on an opposite side of the adjacent spinous processes, such that the spinous processes are sandwiched between the two plates. Each plate **104a,b** includes two grips, each grip **214a,b** comprising part of a clamp adapted for gripping the spinous processes to prevent shifting of the system **100** relative to the spine and to assist in immobilizing the adjacent spinous processes.

[0026] As shown in **FIG. 2B**, a clamp comprises a grip **214a** from a first plate **104a** and a grip **214b** from a second plate **104b**. The grip **214a** from the first plate **104a** is oriented such that the grip substantially opposes a face of a spinous process. The grip **214b** from the second plate **104b** is oriented such that the grip substantially opposes the opposite face of the spinous process. The grips **214a,b** are spaced along the length of the plates **104a,b** such that each pair of grips **214a,b** is positioned about a

spinous process. In other embodiments, and in the same way that spacers **102** are moveable in slots **106**, the grips **214a,b** can be moveably connected to grip slots in the plates **104a,b**, thereby allowing each grip **214a,b** to be moved laterally relative to every other grip **214a,b**, thus allowing each grip **214a,b** to be substantially centered with respect to an associated spinous process.

[0027] Each grip **214a,b** is adjustably connected with an associated plate **104a,b** by a threaded bolt **116** having preferably a hexagonal head for engaging the bolt **116**. Twisting the threaded bolt **116** in a first direction drives the bolt **116**, and consequently the grip **214a,b**, toward the spinous process. Twisting the threaded bolt **116** in a direction opposite the first direction drives the grip **214a,b** away from the spinous process. In other embodiments, the grip **214a,b** can be connected to the plate **104a,b** by a slotted screw. In still other embodiments, the grip **214a,b** can be connected to the plate **104a,b** by a socketed screw. One of ordinary skill in the art can appreciate the myriad of different fasteners that can be used to adjustably connect each grip **214a,b** with an associated plate **104a,b**.

[0028] The bolts **116** are provided through a threaded bore in the plates **104a,b**. Turning the bolts **116** moves the bolts and the grips **214a,b** secured thereto relative to the plates **104a,b**. The ends of the bolts **116** can be either fixedly or rotatably secured to the grips **214a,b**. The bolts **116** can be rotatably secured to the grips **214a,b** as is know in the art. For example, the ends of the bolts can include a circumferential lip that is received in an undercut groove in a bore of the grips **214a,b**. The lip is free to rotate in the groove of the bore. Where the bolts **116** are fixedly secured to the grips **214a,b,** the grips **214a,b** are preferably circular in cross-section (as the bolts **116** are tightened, the grips **214a,b** rotate

relative to the plates **104a,b** and thus relative to the spinous processes). One of ordinary skill in the art can appreciate the different means for adjustably connecting the grip **214a,b** with the plate **104a,b**.

[0029] The plates **104a,b** and threaded bolts **116** can be made of stainless steel, titanium, and/or other biologically acceptable material such as polyetheretherketone (PEEK). In one embodiment, the grips **214a,b** can similarly be comprised of a biologically acceptable material such as stainless steel, titanium, and/or other material such as PEEK, with the surface that comes into contact with the spinous process having a roughened or uneven surface. The contacting surface can, for example, be knurled or it can contain spikes to allow the grips **214a,b** to engage the bone of the spinous processes. In other embodiments, the grips **214a,b** can be comprised of silicon or other biologically acceptable polymer or material (such as presented below with respect to the spacers). The material can be somewhat deformable and can conform to the surface of the spinous processes.

[0030] As shown in **FIGs. 1** and **2A**, the system **100** has a single clamp positioned at each of two spinous processes, each clamp being comprised of two grips **214a,b** on opposite sides of an associated spinous process. However, in other embodiments, a plurality of clamps (with associated grips **214a,b**) can be positioned at selected spinous processes. Thus, for each surface of each spinous process there can be two or more grips. With several grips, each grip can be tightened against a portion of the surface of a spinous process independently of the other adjacent grip that is tightened against a different portion of the same surface of the spinous process. This system can accordingly accommodate uneven surfaces of the spinous processes with each grip tightened against a portion of a surface of a spinous process that is not even with another portion of the surface of the spinous process.

[0031] Referring again to **FIG. 1**, the plates **104a,b** are secured together with pins **110**. A pin **110** can have a threaded bore for receiving a screw or bolt having a hexagonal, slotted, or other type of head at each end of the pin **110**. Alternatively, one or both ends of the pin **110** can be threaded for receiving a nut, or lug for example, or other fastener. The pin **110** can be made of a material similar to the plates **104a,b,** for example, the pin **110** can be made of stainless steel, titanium or other biologically acceptable material. At least one fastener for each pin **110** is tightened so that the pins pull the plates **104a,b** toward one another as desired. Alternatively, the pins **110** can have a main body diameter thicker than the height of a slot **106** with a thinner threaded end for passing through the slot, thereby predefining a space between plates **104a,b**.

[0032] The clamps are adjusted as desired either before or after the fastener(s) of the pins **110** are tightened, thereby allowing the clamps to grip the spinous processes, making the system **100** rigid. A spacer **102** is moveably and rotatably connected with each pin **110** between plates **104a,b**. The spacer **102** is substantially cylindrical in shape with an elliptical cross-section sized to conform to a gap between spinous processes in which the spacer **102** is to be inserted. The elliptical spacer **102** has opposite, slightly curved (or relatively flat) surfaces that can distribute the load placed on the spacer by the spinous processes between which the spacer **102** is positioned. The spacer **102** further has curved ends connecting the slightly curved surfaces. The curved ends point substantially posteriorly and anteriorly. The anteriorly pointing ends approach the spine. In other embodiments the spacer **102** can have an egg-shaped cross-section with the curved end pointing toward the spine being smaller that the curved end pointing posteriorly in order to allow the spacer **102** to more closely approach the spine. In still other embodiments, the spacer

102 can have a cross-section having an ovoid, oval or even spherical shape, for example. One of ordinary skill in the art can appreciate the different cross-sectional shapes with which the spacer **102** can be formed in order to distribute load within the spacer **102**.

[0033] One advantage of using the spacer **102** depicted in **FIG.1** is that the spacer **102** can be partially rotated and repositioned with respect to the system **100** in order to optimize positioning of the spacer **102** between spinous processes. The system **100** is thus designed to account for the various spine structures found in patients. Without having to remove bone from the spine or make multiple adjustments to a hardware system, the spacers **102** and also the grips **214a,b** allow the system **100** to easily conform to the structure of an associated spine. Further, ease of use and placement allow procedures for implanting the system **100** to be carried out more quicky and with less potential trauma to the surgical site. Still further, as indicated above, the spacers **102** can be located closer to the spine where the bone is stronger, thus affording maximum load bearing and stabilizing support relative to the spine. Such load bearing and stabilizing support is advantageous when the system **100** is used as an adjunct to the fusion of adjacent vertebral bodies. It is to be understood that the cortical bone or the outer bone of the spinous processes is stronger at an anterior position adjacent to the vertebral bodies of the vertebra than at a posterior position distally located from the vertebral bodies.

[0034] Still further, for load bearing it is advantageous for the spacer **102** to be close to the vertebral bodies. In order to facilitate this and to accommodate the anatomical form of the bone structures, the spacer **102** rotates relative to the system **100** as the spacer **102** is inserted between the spinous processes and/or urged toward the vertebral bodies so that the spacer **102** is optimally positioned between

the spinous processes and the system **100** is optimally positioned relative to the spinous processes. The shape of the spacer **102** is designed so that it conforms to the area that the spacer **102** is inserted into. However, one of ordinary skill in the art will appreciate that the spacer **102** is not limited to having an elliptical cross-section. For example, the spacer **102** can be substantially spherical in cross-section or egg shaped as set forth above.

[0035] As can be seen in **FIG. 1**, the spacers **102** can be of various sizes. Thus for example, using imaging prior to surgery, the anatomy of the individual patient can be determined and the system **100** assembled to suit the particular patient. Additionally, during surgery the physician can be provided with a kit having different sized spacers **102** and the physician can assemble the system **100** with appropriately sized spacers **102** to fit the anatomy of the patient. In this embodiment the pins **110** can be comprised of rods with threaded bores at each end that receive bolts or screws used to secure the pins between two plates **104a,b** with the spacer **102** rotatably mounted on the pins **110**.

[0036] In other embodiments, the spacer **102** can be comprised of two portions adjustably connected by a hinge to allow expansion of the spacer **102**. For example, as shown in **FIG. 3**, the spacer **102** is comprised of a first portion **330** and a second portion **332** that together have a minor dimension that can be adjusted by rotating a ball **334** connected with a lead screw **336**, such that the ball **334** alternatively forces the minor dimension to expand or allows the minor dimension to collapse. Such a spacer is described in pending U.S. Patent Application No. 60/421,921,entitled "INTERSPINOUS PROCESS APPARATUS AND METHOD WITH A SELECTABLY EXPANDABLE SPACER" by James F. Zucherman, Ken Y. Hsu, and Charles J. Winslow, incorporated herein by reference.

[0037] The spacer **102** can be made of a polymer, such as a thermoplastic, and can be formed by extrusion, injection, compression molding and/or machining techniques. Specifically, the spacer **102** can be made of a polyketone such as PEEK. One type of PEEK is PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. Other sources of this material include Gharda located in Panoli, India. PEEK 450G has appropriate physical and mechanical properties and is suitable for carrying and spreading the physical load between the spinous process. For example in this embodiment the PEEK has the following approximate properties:

Density	1.3 g/cc
Rockwell M	99
Rockwell R	126
Tensile Strength	97
MPaModulus of Elasticity	3.5 GPa
Flexural Modulus	4.1 Gpa

[0038] It should be noted that the material selected may also be filled. For example, other grades of PEEK available and contemplated include 30% glass-filled or 30% carbon-filled PEEK, provided such materials are cleared for use in implantable devices by the FDA or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to unfilled PEEK. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon-filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon-filled PEEK offers wear resistance and load carrying capability.

[0039] As can be appreciated, other suitable biologically acceptable thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible and/or deflectable, have very low moisture absorption and have good wear and/or abrasion resistance, can be used without departing

from the scope of the inventionOther materials that can be used include polyetherketoneketone (PEKK), polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and generally a polyaryletheretherketone. Further, other polyketones can be used, as well as other thermoplastics. Still further, silicon can also be used or the spacer can be made of titanium and/or stainless steel.

[0040] Reference to appropriate polymers that can be used in the spacer can be made to the following documents, all of which are incorporated herein by reference: PCT Publication WO 02/02158 A1, dated January 10, 2002 and entitled Bio-Compatible Polymeric Materials; PCT Publication WO 02/00275 A1, dated January 3, 2002 and entitled Bio-Compatible Polymeric Materials; and PCT Publication WO 02/00270 A1, dated January 3, 2002 and entitled Bio-Compatible Polymeric Materials. Other materials such as Bionate®, polycarbonate urethane, available from the Polymer Technology Group, Berkeley, California, may also be appropriate because of the good oxidative stability, biocompatibility, mechanical strength and abrasion resistance. Other thermoplastic materials and other high molecular weight polymers can be used.

[0041] As mentioned above, each spacer **102** can be connected with a pin **110** that adjustably connects the first plate **104a** with the second plate **104b**. In one embodiment, each plate **104a,b** has three slots **106** spaced and sized such that the slots **106** span approximately the width of the gap between the associated adjacent spinous processes when a patient is standing up. The length of the slots **106** should allow for necessary adjustment of the spacers **102** so that the anatomy of the adjacent spinous processes can be accommodated with the spinous processes immobilized between the spacers **102**. In the system **100**

shown in **FIG. 1**, the middle of three slots **106** is sized larger than the slots **106** on either end of the plates. However, in other embodiments, the slots **106** can be sized relative to one another based on the vertebral bodies that are intended to be immobilized.

[0042] As described above, a pin **110** can be fitted into a slot **106** in each plate **104a,b**. The width of the slot **106** allows the pin **110** to be optimally positioned within the gap between spinous processes, while still being fixable to the plates **104a,b**. The pin **110** can be fixedly connected with each plate **104a,b** by a bolt, screw, nut or other fastener, optionally coupled with a washer. To prevent the plates **104a,b** and pins **110** from slipping and shifting relative to one another, a number of different type of slots can be employed to fix the pin **110** in position. As shown in **FIG. 4A**, one type of slot **106** that can be used is a slot having cut-outs, lobes, or scallops **440** sized such that the cut-outs, lobes or scallops **440** have diameters slightly larger than the diameter of the pin **110**, but are separated such that the adjacent cut-outs, lobes, or scallops are joined at a space narrower than the diameter of the pin **110** so that the pin **110** is prevented from sliding to the adjacent position. Another type of slot **106**, shown in **FIG. 4B**, includes knurls around each slot's periphery, intended to be used with a knurled washer placed between a fastener and a plate **104a,b**. The knurls on the respective surfaces grip each other when the fastener is tightened, preventing the pin **110** from moving in the slot **106**. One of ordinary skill in the art can appreciate the different means for fixing a pin **110** in a slot **106** to prevent the pin **110** from moving relative to the plate **104a,b**.

[0043] In alternative embodiments, the system **100** can comprise one or two plates **104a,b** with spacers **102** rotatably secured thereto (foregoing the use of grips). The system **100** can be implanted and

the position of the spacers **102** can be adjusted relative to the slots **106**, the one or two plates **104a,b,** and the spinous processes in order to immobilize the spinous processes

[0044] **FIG. 5** is a block diagram showing steps for performing a method for inserting a system **100** into a patient in order to immobilize vertebral bodies in accordance with the present invention. As shown in first block **500**, a first, second and third spacer **102** is selected according to the size of the gap between spinous processes that each spacer **102** will occupy. Each spacer **102** is moveably connected with an associated pin **110** (step **502**). An incision is made in the patient proximate to vertebral bodies to be immobilized (step **504**), and the spinous processes and surrounding tissues are exposed. Each spacer **102** is then inserted into position between targeted spinous processes (step **506**) and allowed to rotate and adjust to conform as closely as possible to the contours of the space. A first plate **104a** is inserted into the patient and positioned such that a first end of each pin **110** fits into a slot **106** (step **508**). Each pin **110** is fixedly connected to the first plate **104a** by a fastener, for example a bolt or slotted screw (step **510**). A second plate **104b** is inserted into the patient and positioned such that a second end of each pin **110** fits into a slot **106** (step **512**). Each pin **110** is fixedly connected to the second plate **104b** by a fastener, for example a bolt or slotted screw (step **514**). Finally, the grips **214a,b** are incrementally tightened so that each clamp grips an associated spinous process (step **516**). The incision is closed (step **518**).

[0045] In other embodiments, a method in accordance with the present invention can be applied where there are more or less than three spacers **102**, and/or more or less than two clamps. The configuration of a system **100** will depend on the area intended to be immobilized, and the requirements of the patient.

[0046] Other methods of insertion, include having the system **100** fully assembled prior to insertion. For this method, the surgical site is prepared and then the system **100** is pushed down over the ends of the spinous processes until the system **100** rests in a desired location. At this point the grips **214a,b** are tightened in place about the spinous processes.

[0047] Still alternatively, the system **100** can be partially assembled with the spacers **102** assembled with a first plate **104a**. This subassembly is positioned alongside of the spinous processes and the spacers **102** are urged between the adjacent spinous processes. When the spacers **102** are positioned, the second plate **104b** is secured to the system **100**.

[0048] The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to one of ordinary skill in the relevant arts. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications that are suited to the particular use contemplated. Other features, aspects, and objects of the invention can be obtained from a review of the specification, the figures, and the claims. It is intended that the scope of the invention be defined by the claims and their equivalence.